

§ 493.1443 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and

(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(ii) Have at least 2 years of experience directing or supervising high complexity testing; or

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and—

(i) Be certified and continue to be certified by a board approved by HHS; or

(ii) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least—

(A) Two years of laboratory training or experience, or both; and

(B) Two years of laboratory experience directing or supervising high complexity testing.

(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory

director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or

(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or

(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993; 59 FR 62609, Dec. 6, 1994; 62 FR 25858, May 12, 1997; 63 FR 55034, Oct. 14, 1998; 65 FR 82944, Dec. 29, 2000; 68 FR 3713, Jan. 24, 2003]

§ 493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§ 493.1447, 493.1453, 493.1459, and 493.1487, respectively.

(b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;